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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,064	10/31/2001	Carolyn Elizabeth Lister	01288.0016	4565

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EXAMINER

HELMER, GEORGIA L

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,064	LISTER ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>18 Aug 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

1. The Office acknowledges receipt of Applicant's Response; dated 18 August 2005.
2. Applicant has requested amendment of claim 7, addition of new claims 16 and 17, and cancellation of claim 14. Claims 1-12, 16 and 17 are pending, and are examined in the instant action.
3. The "Statutory Declaration" of Colin Eady dated 23 March 2005, including the reference (Eady et. al., *Agrobacterium tumefaciens* mediated transformation of *Allium porrum* (leek) and *Allium sativum* (garlic), Plant Cell Reports, 2005, in press) are acknowledged.
4. This action is made FINAL.
5. All rejections not addressed below have been withdrawn.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

7. The IDS filed 18 August 2005 is acknowledged and a signed and dated copy is enclosed therewith.

Claim Rejections - 35 USC § 112, first paragraph

8. Claims 1-12, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method set for in the specification whereby embryos of onion are cocultured with *Agrobacterium*, selected to produce transgenic plant material, which is then cultured to produce secondary embryos, and obtaining a transgenic onion plant from the secondary embryos wherein

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the transformation method is carried out without passage through a callus phase, (the method set forth in the specification p. 5, line 11, to p.6, line 14) does not reasonably provide enablement for the broad scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In the previous Office Action, claim 3 was objected as being dependent upon a rejected bases claim, but would be allowable if rewritten in independent form including all the limitations of the base claims and any intervening claims. However, some confusion exists because a second method is referred to in the specification (p. 4, Example 4, says "Onion immature embryos were transformed according to the protocol of Eady et. al. (1999)"). However, no information of what or where this reference is. Therefore, the Office is unable to determine what the transformation method of Example 4, Eady et. al. (1999), consists of, and what is the relationship of this Example 4 method to the method in the specification, pages 5-6. Accordingly, the enablement rejection is drawn to methods other than exemplified in specification p. 5-6. This rejection is applied to new claims 16 and 17, which are limited to onion (*Allium cepa*), but which have the same problem as discussed above. Applicant is encouraged to clarify these issues.

Applicant traverses saying primarily (Response, p. 9) that the Eady 2005 article "demonstrates the successful use of the method set forth in the present application for the transformation of two additional *Allium* species", leek and garlic; that the results" highlight the premise that an application disclosing even one species encompassed

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within a genus may be sufficient for the purposes of “ of § 112.1st ¶ , to “constitute disclosure of the entire genus”.

The “Statutory Declaration” of Colin Eady dated 23 March 2005 (hereafter “Eady Declaration 2” to distinguish it from the earlier Eady Declaration in this case) has been carefully considered, as has the cited reference (Eady 2005), and is found to be not persuasive.

Eady states that (Eady Declaration 2, ¶ 2) “the technique developed to transform onions (*Allium cepa*) as described in application US 09/890,064 can be applied to other species. Eady (¶ 3) further states that he has demonstrated that the method of the instant case is applicable to other *Allium* species including *Allium porrum* (leek) and *Allium sativum* (garlic), citing the in-press publication ((Eady et. al., *Agrobacterium tumefaciens* mediated transformation of *Allium porrum* (leek) and *Allium sativum* (garlic), *Plant Cell Reports*, 2005, in press). Eady (¶ 5) states that “the publication referred to under paragraph 3 is”..”evidence that the technique described in the present application can be applied to other species of *Allium*, and that therefore the description of US 09/890,064 is enabling for other species of *Allium*”.

Applicant's traversal is unpersuasive. The submitted reference, Eady et. al., 2005, sets forth that “Transgenic leek and garlic plants have been recovered by the selective culturing of immature leek and garlic embryos via *Agrobacterium* mediated transformation using a method similar to that described by Eady et. al. (*Plant Cell Reports* vol 19, pages 376-381, 2000)”. This reference is dated 2000. So the post filing dated 2005 reference refers to a post filing date reference dated 2000. However

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the filing date of the priority document , New Zealand 333992, is 29 January 1999, which is nearly a year before the earlier of these two cited references. Therefore the post-filing date references cannot be used to support enablement as of the date of filing.

See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

What needs to be provided is a statement to the effect that the post-filing procedure(s) used are the same as those disclosed in the instant specification.

Applicant traverses saying primarily that (Response, p. 10) "to the extent that the Office bases its current 112, first paragraph , rejection on 'Applicant's argument filed 09 September 2004' ,...the Applicants note that such argument may be no longer applicable when referred to generically,that the Applicants have amended its claims several times"...

Applicant's traversal is unpersuasive. The Office acknowledges such amendments.

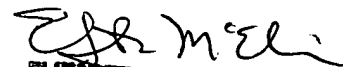
Remarks

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 10:30-6:30 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Unit 1638
October 31, 2005


ELIZABETH MCELWAIN
PRIMARY EXAMINER